



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE PATENT OPERATION

In re Application of:

Unchalee Kositprapa et al.

Serial No.: 10/664,803

Group Art Unit: 1615

Filed: 09/19/2003

Examiner: Silverman, Eric E.

For: NOVEL PHARMACEUTICAL FORMULATION CONTAINING A BIGUANIDE AND A THIAZOLINEDIONE DERIVATIVE

New York, NY 10036 August 27, 2007

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

The following references are submitted by the applicant with the accompanying Forms PTO/SB/08A.

Document
Designation
AA
U.S.P. 4,891,223

AB U.S.P. 5,840,335

AC U.S.P. 5,955,106

08/30/2007 WASFAW1 00000017 10664803

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180.00 OP

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on August 27, 2007

Nicholas P. Chiara, Reg. No. 52,737

Document Designation

AD

U.S.P. 5,965,584

ΑE

U.S.P. 6,099,859

AF

U.S.P. 6,153,632

AG

U.S.P. 6,166,042

AH

U.S.P. 6,166,043

ΑI

U.S.P. 6,172,090

AJ

U.S.P. 6,291,495

ΑK

U.S.P. 6,403,121

AL

U.S.P. 6,475,521

AM

U.S.P. 6,495,162

AN

U.S.P. 6,524,621

ΑO

U.S.P. 6,660,300

AP

U.S.P. 6,780,432

AQ

U.S.P. 6,790,459

AR

U.S.P. 6,866,866

Document Designation

BA

U.S. Pub. 2004/0081697

BB

U.S. Pub. 2005/0074490

BC

U.S. Pub. 2006/0057202

BD

U.S. Pub. 2006/0141023

BE

U.S. Pub. 2006/0286168

CA WO 2001/035941 Relates to a pharmaceutical composition comprising

a thiazolidinedione and metformin HCl and a pharmaceutically

acceptable carrier.

CB

Relates to providing a process for producing pioglitazone

WO 2004/067001

HCl coated preparation.

CC

Relates to providing a process for producing pioglitazone

WO 2004/006921

HCl coated preparation

In accordance with current United States Patent and Trademark Office practice no copies of the above listed United States Patents or published United States Applications are filed herewith. Full copies of non- United States Patent Documents are filed herewith. It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made of record therein.

The fee of \$180.00 that is required for consideration of this Information Disclosure Statement is enclosed within. The Commissioner is hereby authorized to charge Deposit Account No. 08-1540 for any deficiency or credit any overpayment. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Nicholas P. Chiara

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INFORMATION DISCLOSURE

Complete if Known

Application Number 10/664,803

Filing Date September 19, 2003

First Named Inventor Kositprapa et al.

Art Unit 1615

Examiner Name Silverman, Eric E.

Attorney Docket Number 141-424

(Use as many sheets as necessary)
Sheet 1 of 2

U. S. PATENT DOCUMENTS Name of Patentee or Pages, Columns, Lines, Where Examiner Cite **Document Number** Publication Date MM-DD-YYYY Initials* No. Applicant of Cited Document Relevant Passages or Relevant Figures Appear Number-Kind Code^{2 (# known)} US- 4,891,223 AA 01-02-1990 Ambegaonkar et al. ^{US-} 5,840,335 AB 11-24-1998 Wenzel et al. ^{US-} 5,955,106 09-21-1999 Moeckel et al. AC ^{US-} 5,965,584 10-12-1999 AD Ikeda et al. ^{US-} 6,099,859 08-08-2000 ΑE Cheng et al. ^{US-} 6,153,632 11-28-2000 Rieveley AF AG ^{US-} 6,166,042 12-26-2000 lkeda et al. ^{US-} 6,166,043 12-26-2000 lkeda et al. AH US-6,172,090 01-09-2001 Ikeda et al. ΑI ^{US-} 6,291,495 09-18-2001 AJ Rieveley ^{US-} 6,403,121 ΑK 06-11-2002 Adjei et al. ^{ūs-} 6,475,521 11-05-2002 Timmins et al. AL ^{US-} 6,495,162 12-17-2002 Cheng et al. AM US-6,524,621 02-25-2003 Adjei et al. AN AO us- 6,660,300 12-09-2003 Timmins et al. US-6,780,432 08-24-2004 Cutie et al. AP ^{US-} 6,790,459 Cheng et al. 09-14-2004 AQ ^{US-} 6,866,866 AR Chen et al. 03-15-2005 US- 2004/0081697 04-29-2004 BA Lewis et al.

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear		
		Country Code ^{3 -} Number ^{4 -} Kind Code ⁵ (<i>if known</i>)	MM-DD-YYYY			T	

Examiner		Date	•
Signature		Considered	
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or so for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known		
Application Number	10/664,803	
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			U. S. PATEN	T DOCUMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (# known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	ВВ	^{US-} 2005/0074490	04-07-2005	Lin et al.	
	ВС	^{US-} 2006/0057202	03-16-2006	Antarkar et al.	
	BD	^{US-} 2006/0141023	06-29-2006	Trehan et al.	
	BE	^{US-} 2006/0286168	12-21-2006	Koike et al.	
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Examiner Initials*	Cite No.1	Foreign Patent Document Programment Progra	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code ^{3 -} Number ^{4 -} Kind Code ⁵ (if known)	MM-DD-YYYY	,,,	Or Relevant Figures Appear	T⁵
	CA	WO 2001/35941	05-25-2001	Lilliott et al.		
	СВ	WO 2004/067001	08-12-2004	Ohkouchi et al.		
	СС	WO 2004/006921	01-22-2004	Koike et al.		
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Examiner		Date	
Signature	•	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Senter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Skind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached.

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